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10/582,422	06/09/2006	Hoi-Ying N. Holman	LBNL-238 (IB-1867-US)	4848
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NEW YORK, NY 10103-3198				
EXAMINER				
BRUTUS, JOEL F				
ART UNIT		PAPER NUMBER		
3768				
NOTIFICATION DATE		DELIVERY MODE		
08/24/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyipdocket@fulbright.com

Office Action Summary

Application No.

10/582,422

Applicant(s)

HOLMAN, HOI-YING N.

Examiner

JOEL F. BRUTUS

Art Unit

3768

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 29-40 and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (US Pat: 5,293,872) in view of Dukor et al (Pub. No.: US 2002/0164810).

Regarding claims 29, 34, and 42-43 and 50, Alfano et al teach a system for in vivo or in vitro testing of a cardiovascular tissue sample to determine if the tissue is calcified atherosclerotic, fibrous atherosclerotic or normal [see column 8 lines 15-18]

that is pertinent to the claimed invention [see abstract]. Alfano et al teach an endoscope 141 sized and shaped to fit within an artery or other blood vessel. Alfano et al further teach the endoscope includes an outer cuff 143 that includes four channels and an optical fiber bundle 147 is mounted within a first channel is used to illuminate the interior of the artery and a fiber optic bundle 149 mounted within the endoscope is used to convey infrared light and fluorescence- inducing light (e.g. ultraviolet light, visible light) to the arterial tissue and to collect the resulting Raman scattered light for use in detecting calcified atherosclerotic tissue and the resulting fluorescence for use in detecting fibrous atherosclerotic tissue or normal tissue respectively [see column 9 lines 8-28]. Alfano et al use mid IR ranges of wavenumbers to diagnose atherosclerosis [see abstract].

Alfano et al teach a Raman spectral analyzer and fluorescence spectrum analyzer produce spectrum of the samples and convert them into electronic signal an electronic signals which are transmitted to preprocessing unit 69 into a computer to determine if a tissue is normal or calcified atherosclerotic [see column 8 lines 5-60]. Alfano et al teach the computer analyzer compares the intensity ratio for the tissue being tested with standard ratios from calcified atherosclerotic tissue and from fibrous atherosclerotic tissue or normal tissue [see column 6 lines 39-50 and column 7 lines 1-15]. The computer analyzer is used as the comparator to compare selected wavenumbers with absorbance peak with a normal to determine whether a tissue and/or blood vessel is atherosclerotic and data/spectra from normal tissue as considered or used as reference data/spectra (emphasis added).

Alfano et al don't refer to selected wavenumbers as mid-IR in their description.

However, as in claims 42-43 mid-IR range between 4000 cm^{-1} to about 400 cm^{-1} ; Alfano et al teach using wavenumbers 1659 cm^{-1} and 957 cm^{-1} which fall in the range of 4000 cm^{-1} to 400 cm^{-1} [see column 8 lines 1-14 and see figs 2-4].

Nevertheless, Dukor et al teach mid-IR absorbance spectra around 1280 cm^{-1} [see figs 2-3, 0015-0016, 0024]; a device can be used to diagnosed for malignancy; inflammatory processes [see 0033]. Wavenumbers around 1280 cm^{-1} is effective for pathology detection [see 0009]. Dukor et al also teaches a computer with a software application for IR imaging data collection and spectroscopy analysis [see 0060].

Therefore, one with ordinary skill in the art would be motivated to combine Alfano et al and Dukor et al and use mid-IR wavenumbers around 1280 cm^{-1} is effective for pathology detection [see 0009, Dukor et al]. Inflammatory processes and degenerative conditions [see 0033]; extracellular material such as blood, plasma, saliva, secretions, urine and sweat imply determining a chemical composition (emphasis added). One would have been motivated to determine a chemical composition and cellular condition; for the purpose of having an accurate and reliable diagnosis.

Regarding claims 30-33, 35-36, all other limitations are taught asset forth by the above teaching.

Alfano et al teach absorbance peaks of wavenumbers 1659 cm^{-1} and 957 cm^{-1} and range of 700 cm^{-1} to 1900 cm^{-1} [see column 8 lines 1-14 and see figs 2-4] which fall in the range of 4000 cm^{-1} to 400 cm^{-1} ; 1690-1610 cm^{-1} .

With regards to resolved map; Alfano et al teach a map of generated spectral signals from different locations within a blood vessel [see fig 4].

Regarding claim 37, all other limitations are taught as set forth by the above teaching. Alfano et al further teach an interferometer [see column 6 lines 39-50 and column 7 lines 1-15].

Regarding claims 38 and 44, all other limitations are taught as set forth by the above teaching. Alfano et al further teach that the endoscope includes a cuff 143 surrounds all but the tip of a cable 145 [see fig 10], which includes four channels; cable 145 has a tip or tip array [see fig 10]. Alfano et al also teach an optical fiber bundle 147 (used as a source fiber, emphasis added); a fiber optic bundle 149 (used as a detector, emphasis added) for use in detecting calcified atherosclerotic tissue, fibrous atherosclerotic tissue or normal tissue [see column 9 lines 8-28].

With regards to the fiber optic cable of claim 44, Alfano et al disclose a cable 145 in fig 10 that includes four channels at its tip [see fig 10]. Alfano et al also teach that cable 80 is similar in construction with fiber optic bundle 149 [see column 9 lines 16-17]. Therefore, cable 80 has to be a fiber optic cable (emphasis added).

Regarding claim 47, all other limitations are taught as set forth by the above teaching. Alfano et al teach a spectrophotometer [see column 5 lines 26-27].

Regarding claim 40, all other limitations are taught as set forth by the above teaching.

Alfano et al teach a liquid nitrogen cooled indium gallium arsenide photodiode type detector [see column 5 lines 21-23].

Regarding claims 45-46, and 48-49, all other limitations are taught as set forth by the above teaching.

Alfano et al further teach the endoscope which includes the cable would be used as the catheter means for insertion in body lumens (emphasis added). Alfano et al teach spectrum analyzer, fluorescence analyzer, and endoscope probing cable [see fig 9]. The fiber cable transmits reflected light to the spectrum analyzer for performing spectroscopic analysis (emphasis added).

Alfano et al don't explicitly mention whether the optical cable 145 is rotatable within the body lumen.

However, it is well known in the art that catheters and endoscope are rotatable within a body lumen such as a blood vessel (emphasis added).

Therefore, it is inherent that cable 145 within the endoscope rotates radially within the blood vessel to acquire data at various locations; thus performing 360 degrees spectral analysis (emphasis added).

Regarding claim 39, all other limitations are taught as set forth by the above teaching.

Alfano et al don't teach a tuning system.

However, Dukor et al teach an acousto-optical tunable filter or liquid crystal tunable filter could be used to switch back and forth between the wavelengths of the two baselines points to obtain slope measurement [see 0063].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Alfano et al and Dukor et al reference; for the purpose of using a desired wavenumber.

4. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (US Pat: 5,293,872 in view of Dukor et al (Pub. No.: US 2002/0164810) as applied to claim 34 above and further in view of Corenman et al (US Pat: 4,817,013).

Regarding claim 41, all other limitations are taught as set forth by the above combination.

Alfano et al don't teach customized bandwidth and special gain for DC or AC preamps.

However, Corenman et al teaches preamp [see 6C]; fig 4A shows AC/DC separation circuit in the amplifiers that receive signal output from three infrared detectors.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Alfano et al and Corenman et al references; for the purpose of providing a more efficient system by improving its performance.

Response to Arguments

5. Applicant's arguments filed 4/1/10 have been fully considered but they are not persuasive.

The affidavit filed on 4/1/2010 has been entered; in the affidavit, Applicant explains that Alfano et al use Raman spectroscopy method and explain that the present invention uses mid IR; and further points out how Raman and mid IR interact with normal tissue and atherosclerotic constituents and further argues that none of the references teach mid IR bands as diagnostic marker for atherosclerosis disease.

The examiner disagrees because Alfano et al use mid IR ranges of wavenumbers as of in claim 31 to diagnose atherosclerosis [see abstract].

In the affidavit, Applicant also argues that Dukor's method doesn't teach diagnosing atherosclerosis and they can't be combined and none of the references show narrow wavenumber regions identified in the present invention.

The Dukor's reference is relied to show proof of mid IR ranges and relied on for atherosclerosis detection. Mid IR range is taught by Alfano et al [see column 8 lines 1-14] and Alfano use wavenumber ranges (as of mid IR) to diagnose atherosclerosis. Applicant discloses mid IR range of 3500 to 400 cm^{-1} ; however, Alfano et al teach range of 4000 to 400 cm^{-1} [see column 18 lines 1-14].

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is

(571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768